Winston H. Hickox
Secretary for Environmental Protection

Department of Pesticide Regulation

Paul E. Helliker, Director
830 K Street • Sacramento, California 95814-3510 • www.cdpr.ca.gov

Gray Davis
Governor

M E M O R A N D U M

TO: Karen Fletcher, Registration Specialist HSM-99016
Pesticide Registration Branch

FROM: Tom Thongsinthusak, Staff Toxicologist **[original signed by T. Thongsinthusak]**
Worker Health and Safety Branch
(916) 445-4267

DATE: August 17, 1999

SUBJECT: BRAND NAME: Chlorothalonil
ACTIVE INGREDIENT: Chlorothalonil
COMPANY NAME: Zeneca, Inc.
I.D. NUMBER: SBRA-177578-E
RECORD NUMBER (RN): 169026
DATA PACKAGE NUMBER (DPN): 275-342
EPA REGISTRATION NUMBER: 10182-0-
TITLE: CHLOROTHALONIL – RISK ASSESSMENT REBUTTAL: ZENECA RESPONSE TO CALEPA DPR DRAFT CHLOROTHALONIL RISK CHARACTERIZATION DOCUMENT (DECEMBER 10, 1998)

Zeneca, Inc. provided comments shown in the above document for the Department of Pesticide Regulation (DPR) draft chlorothalonil risk characterization document. The Toxicology Branch has responded to comments regarding toxicological issues (Lim, 1999). This memorandum addresses comments pertaining to chlorothalonil exposure assessment, including inhalation exposure to respirable material, recent field exposure study conducted during aerial and groundboom applications, and inhalation exposures for workers.

Page 3. Zeneca contended that workers are not exposed to significant amounts of respirable (or volatile) material during mixing, loading and application of liquid formulations of a comparatively nonvolatile substance such as chlorothalonil. Zeneca included a table showing percentages of total inhalable and respirable ranges for commonly used hydraulic nozzles (Arnold, 1997).

The submitted document contained droplet size distribution data obtained from Arnold (1997). We do not know whether the test system is relevant to aerial, groundboom, and airblast applications of chlorothalonil. The cited reference has not been submitted to DPR since it was a personal communication. In 1998, WH&S reviewed Zeneca's submitted report on contribution of aerosols generated during simulated mixing and loading Bravo® 500 SC to operator inhalation exposure (Thongsinthusak, 1998). In that study, slides of a cascade impacter were used to collect aerosols that had mean diameters of >13, 13.0, 4.0, and 1.7 µm. Chlorothanil on those slides, except for chlorothalonil with mean diameters >13 µm, was analyzed by gas chromatography. However, the percentage by weight for those particle sizes could not be calculated because the

total amount of aerosols generated was not known. The review memorandum concluded that inhalation exposures contained in the chlorothalonil exposure document, HS-1475 (Thongsinthusak *et al.*, 1996) could not be refined to reflect exposure to the upper (extrathoracic deposition) or lower respiratory tract (thoracic deposition). As shown in the exposure document, inhalation exposure estimates were obtained from actual field studies using chlorothalonil and surrogate chemicals. These estimates include different particle sizes trapped by air sampling tubes.

Page 5. Zeneca stated that the previous submitted study (Diamond Shamrock, 1980) was an old study with considerable uncertainty over the validity of the data. This study should be replaced by a recent submission (King et al., 1996). Zeneca suggested that flagger exposure should be obtained from PHED.

WH&S received the report of the recent study conducted by King *et al*. (1996) on May 24, 1999. We will review this study and decide if exposure data from the new study should replace the old study that was conducted by Diamond Shamrock Corp. (1980). We realize that the previous study was not perfect. However, the Pesticide Handler Exposure Database (PHED) surrogate exposure guide incorporated many studies that were performed before the mid-80's, and virtually, all studies were not done in accordance with the current U.S. EPA GLP standards. Most field exposure studies used in PHED were done using patches where approximately 75% of patch data were nondetectable. Furthermore, many exposure studies lasted for a short time, e.g., 10-15 minutes, and the amount of a.i. handled was <10 lbs.

Page 9. Risk Characterization. Zeneca reiterated the irrelevance of the acute inhalation toxicity hazard study to the risk of inhalation exposure to worker. MOEs were shown based on Zeneca's calculated inhalation exposure for mixer-loaders (groundboom and aerial) and flaggers (aerial).

WH&S will likely determine inhalation exposures of handlers from the new study. Dermal and inhalation exposures of flaggers from the previous study may be retained or obtained from PHED because the new study did not include a flagger exposure study.

Inhalation exposure estimates shown in HS-1475 reflect total amounts of chlorothalonil deposited in air sampling tubes, and the total estimates do not represent respirable aerosols. The percentage of respirable aerosols (particle sizes are approximately up to 8 μm) of inhalation exposure estimates may be small compared to what was used in the acute inhalation toxicity study.

References:

Arnold, A. C. 1979. British Crop Protection Council. Central Testing Scheme. "Droplet spectra for the 20 most commonly used hydraulic nozzles. Personal communication. April 23.

Diamond Shamrock Corp. 1980. Applicator exposure study. DPN 275-072, RN 941753.

King, C., Prince, P. M., and Wiedmann, J. L. 1996. Commercial mixer/loader exposure study with chlorothalonil. DPN 275-341, RN 168381.

Lim, L. O. 1999. Chlorothalonil. A memorandum dated June 4, 1999 to G. Patterson. Toxicology Branch, DPR.

Thongsinthusak, T., Blewett, T. C., Ross, J., and Krieger, R. I. 1996. Estimation of exposure of persons in California to pesticide products that contain chlorothalonil. HS-1475. Worker Health and Safety Branch, DPR.

Thongsinthusak, T. 1998. Inhalation exposure of chlorothalonil. A memorandum dated October 8, 1998 to John Ross. Worker Health and Safety Branch, DPR. HSM-98007.

cc: Ann Prichard
Chuck Andrews

(Memos/HSM-99016)